



Name :

Roll No. :

Invigilator's Signature :

CS/M.PHARM/SEM-1/MPT-115(1)/2011-12

2011

QUALITY OF ASSURANCE-I

Time Allotted : 3 Hours

Full Marks : 70

The figures in the margin indicate full marks.

Candidates are required to give their answers in their own words as far as practicable.

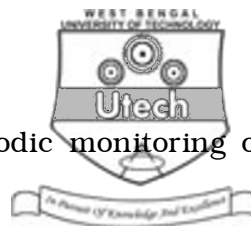
GROUP – A

(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following :

10 × 1 = 10

- i) For the preparation of purified water I.P. the microbiological specification of the potable water used is not more than
- a) 500 cfu/ml
 - b) 200 cfu/ml
 - c) 100 cfu/ml
 - d) none of these.
- ii) Diluted disinfectants shall bear the label
- a) use within
 - b) use before
 - c) use after
 - d) none of these.



- iii) The recommended frequency of periodic monitoring of particulate in air is
- a) three monthly b) daily
- c) six monthly d) yearly.
- iv) Air pressure differentials in aseptic room should be monitored
- a) yearly b) daily
- c) six monthly d) three monthly.
- v) In case of metered dose inhaler where the products on clean components are exposed, the area shall be supplied with filtered air of grade.
- a) C b) A
- c) B d) D.
- vi) Cetrimide is type of surface active agent.
- a) anionic
- b) nonionic
- c) cationic.
- vii) Chlorhexidine acetate is used in formulation.
- a) Mouthwash b) Shampoo
- c) Toothpaste d) Cold cream.
- viii) The implication of purchased materials on finished good will be evaluated by
- a) the organization b) storekeeper
- c) drugs inspector d) none of these.

- ### GROUP – B

Answer any *three* of the following. $3 \times 5 = 15$

- 40444



GROUP – C

(Long Answer Type Questions)

Answer any *three* of the following. $3 \times 15 = 45$

7. a) Give the basic requirements of a good dentrifice. Write in brief about the agents that may be used to attain the desirable characteristics of a good dentrifice. Discuss their advantages and disadvantages.

b) What are the uses of mouthwashes ? Write in brief about the formulation of such preparations in reality. Give the components and specific requirements of such agents in actual situation. $(2 + 5) + (2 + 3 + 3)$
8. Describe the general requirements for quality management system and requirements for products. Elaborate quality management system approach. $9 + 6$
9. a) Describe the salient points that have to be considered for designing a layout for factory premises.

b) Describe HVAC system. $10 + 5$
10. a) Describe the factors to be considered for installation of equipment.

b) Write a note on cleaning and maintenance of equipment. $9 + 6$
11. Describe in detail about in process quality control test of tablet dosage form.

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